Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

The Competition Authority - Consultation Document – Consultation on Collective Action in the Community Pharmacy Sector – Invitation to Comment

A Submission by the Health Service Executive (HSE), 28th November 2008

1. Background and Context

The HSE currently has arrangements in place with almost 1,600 contractors across the State for the provision of community pharmacy services under the 1970 Health Act, to the eligible population across the various Community Drug Schemes (which include the General Medical Services Scheme (GMS), the Drugs Payment Scheme (DPS), the Long Term Illness Scheme (LTI), the High Tech Medicines Scheme and the Methadone Treatment Programme). The current Agreement with community pharmacy contractors came into effect in 1996.

In 2007 payments totalling almost €1.9bn were made to Community Pharmacy Contractors by the HSE. The costs of the community drug schemes have increased by some 400% over the past ten years. It is also of note that the fees and mark up paid to community pharmacy contractors by the HSE's Primary Care Reimbursement Service (PCRS) increased from €207m in 2002 to €371m in 2007 (an increase of some 79%).

Community Pharmacy Contractors, as an important element in the spectrum of professional services provided in the health care delivery system, provide their services at the end of the pharmaceutical supply chain. The other parts of the chain are the Pharmaceutical Manufacturers and the Pharmaceutical Distributors (Wholesalers). The principal activity of the Community Pharmacy Contractor is the dispensing of prescription medicines to eligible patients accompanied by professional advice on their use and safety.

Given that the Pharmacy Contract governs the relationship between the State and pharmacy contractors, regulating the operation of community pharmacy services throughout the country, it has significant economic effects, including effects on inter-state trade. The contractual arrangements with community pharmacists constitute a very large part of the HSE's business, and enable the delivery of important public health services, as evidenced by the number of contractors, the level of prescription items being reimbursed on an annual basis by the HSE (in excess of some 60 million in 2007) and the level of payments made to contractors by the HSE each year (some €1.9bn in 2007). Taking account of the broad economic and public health context, the HSE welcomes the opportunity being afforded to it to make a submission to The Competition Authority as part of its Consultation process on "Collective Action in the Community Pharmacy Sector".

The submission is in the form of a response to each of the 7 questions posed in the Consultation Document.

2. Questions posed by The Competition Authority

The following are the comments offered by the HSE in respect of Questions One through Seven posed by the The Competition Authority:

Q 1: Is there a place for the messenger model in structuring the relationship between pharmacy contractors and the HSE? Can the messenger model be adapted to secure a contract for the provision of community pharmacy services that is acceptable to both pharmacy contractors and the HSE (and ultimately, taxpayers)?

Comment

We set out below our comments in relation to the messenger model. However, we have to preface these with the observation that, in the view of the HSE, the messenger model is difficult, if not impossible, to reconcile with the provision of the current Pharmacy Contract that governs payments. Clause 12 of the Pharmacy Contract provides that;

> "*The board shall in consideration of the service provided by the pharmacy contractor in accordance with these terms and conditions and on foot of claims made in the form and at the times directed by the Minister, make payments or arrange for payments to be made to the pharmacy contractor for prescriptions dispensed at his/her contracted community pharmacy in accordance with such rates as may be approved or directed by the Minister from time to time after consultation with the Pharmaceutical Contractors' Committee".*

As confirmed by Judge Finlay Geoghegan in *Hickey & Others v The HSE,* the payments provided for under Clause 12 are capable of being varied from time to time unilaterally by the Minister, but only after consultation with the Pharmaceutical Contractors' Committee of the IPU[1]. It is evident that, given its lack of independence, the IPU could not act as a messenger for the purposes of the messenger model. We do not, accordingly, see a place for the messenger model within the Clause 12 mechanism.

In our view, the mechanism for variation of price in the Pharmacy Contract is an example of "Fee setting by the Payor". This was one of the permitted fee setting mechanisms identified by the Competition Authority in its Consultation on Guidance in respect of Collective Negotiations relating to the setting of medical fees in January 2006.

However, in the event that the provisions of Clause 12 were *amended* to provide for fee setting by the Minister after consultation with individual pharmacy contractors (rather than with the IPU)[2], we do see room for possible use of the messenger model, and it is within that context that we make the comments below.

[1] See for example paragraphs 84 and 90 of the judgment.
[2] See further our answer in respect of Question 3

While we recognise that a messenger model can be structured in many different ways, the way we consider that it could be tailored to a consultation by the HSE/Minister with individual pharmacy contractors would be as follows:

- The HSE/Minister engages an independent third party called a 'messenger';
- The HSE/Minister, either directly or through the messenger, sends the draft contract and fee structure to individual pharmacy contractors, requesting their views on pricing.
- The messenger obtains the response, individually, from each pharmacy contractor as regards the level of fees they will accept; the pharmacy contractor may be required to provide financial information and information in relation to the nature and profile of its practice etc. in order to support the position it is taking.[3]
- The messenger collates the information and conveys it to the HSE/Minister[4];
- There may be further communication between the HSE/Minister and the pharmacy contractor through the messenger.
- The HSE/Minister then issues its schedule of fees for services to individual pharmacy contractors, either directly or through the messenger;
- Each pharmacy contractor decides individually whether or not to participate;
- The messenger does not negotiate fees for the pharmacy contractors nor do the pharmacy contractors collectively develop a fee schedule for the HSE/Minister;
- There is no sharing of fee information by the messenger among the pharmacy contractors;
- Pharmacy contractors do not engage in or threaten a boycott or other collective anti-competitive conduct in the event that they are not fully satisfied with the final offer made.

As pointed out in the Consultation Document, the messenger model has the potential to be a very useful tool in ensuring that the HSE/Minister is fully informed of the views of individual contractors. However, in the view of the HSE, the success of the messenger model would be conditional on the following factors:

- *Absence of anti-competitive conduct by pharmacy contractors.*

[3] The HSE/Minister might, alternatively, structure the process so that it issues the first offer on pricing, and asks the pharmacy contractor to accept or reject that offer, or submit a counter proposal.

[4] As pointed out by the Authority, the information could be structured in such a way as to facilitate the development of a tiered fee, eg taking particular account of the position of pharmacists operating in deprived urban or isolated rural areas.

For the application of this model to be found to be legal it must facilitate independent, unilateral (rather than collective) engagement by the pharmacy contractors with the HSE/Minister. The safeguards discussed in the answer to Question 2 may reduce, but may not entirely remove, the risk that the process will be distorted and undermined by anti-competitive conduct by pharmacy contractors.

- *Bona fide participation by all or a large majority of pharmacy contractors*

In order to be successful, pharmacy contractors would need to participate in the messenger model in good faith and in accordance with the rules of engagement laid down at the outset of the process.

If, by and large, the fee levels conveyed by pharmacy contractors (potentially in the region of 1,600 views) to the State via the messenger, are true and accurate indications of acceptable fee levels, then the State will acquire good information which can guide the setting of fees that are likely to have a desired level of acceptability among the pharmacy contractors.

Good faith is required on both sides in order that the model would work. The value to the State of the information obtained, and the usefulness of the process overall, would be undermined if the pharmacy contractor was not willing to submit a realistic offer and, where required, economic evidence to support its position.

- *Clear time-lines and rules of engagement*

The messenger model has been criticised for being cumbersome and difficult to implement[5]. There would need to be clear time-lines and rules of engagement set down at the outset of the process.

- *Independence of the messenger*

The independence of the messenger is important to avoiding the situation that has arisen a number of times in the US, where those participating in the messenger model were ultimately prosecuted due to the fact that the arrangement was found to create or facilitate an agreement amongst competitors on price or price related terms. It is our understanding that, if the messenger is found to have coordinated pharmacy contractors' responses, shared views amongst contractors, expressed an opinion on the terms offered, collectively negotiated or used its own judgement as to the attractiveness of an offer in order to decide whether or not to convey it[6], the messenger is likely to be found to have facilitated coordinated conduct by the pharmacy contractors. The independence of the messenger is therefore critical.

- *The ultimate decision on fee levels must remain with the State, without any threat of boycott or other concerted action by pharmacy contractors.*

[5] "Brown Bag Program: Messed Up Messenger Models and How to do Them Right", Antitrust, September 2003, accessible at: www.antitrustsource.com.

[6] Page 161 Chapter 9, DOJ/FTC Statements of Anti-trust Enforcement Policy in Health Care, August 1996

If the messenger model was employed for the purpose of consulting pharmacy contractors (rather than the IPU) prior to a decision under Clause 12 of the Pharmacy Contract, this could not change the position that, as confirmed by Judge Finlay Geoghegan in *Hickey & Others v The HSE,* the fees are capable of being varied by a unilateral decision of the Minister. No agreement is required.

In order for that decision of the Minister to be genuinely unilateral and independent, there could be no threat of boycott or other collective anticompetitive conduct by pharmacy contractors.

It should also be emphasised that, in addition to consulting individual pharmacy contractors, the State would seek input from economic experts and possibly other stakeholders before finalising its decision in relation to the fee level to offer. If the data provided by pharmacy contractors via the messenger is accurate, it would be hoped that an economic analysis conducted by the State would support that data. However, it would have to be made clear that, whether or not this is the case, the decision made by the State on fees must, while taking into account the views of pharmacy contractors, be based on sound economic analysis.

It must also, obviously, take into account budgetary constraints; the State does not have a blank cheque as regards the ultimate offer that will be made to pharmacy contractors.

In summary, the HSE's view is that it does not see scope for use of the messenger model under the current Pharmacy Contract, Clause 12 of which sets out the agreed mechanism for fee setting by the payor after consultation with the IPU. However, the HSE recognises that the messenger model can offer benefits to both service providers and payors and, in the event that Clause 12 was amended to provide for fee setting by the HSE/Minister after consultation with individual pharmacy contractors (rather than the IPU), the HSE would be open to considering its use. However, the HSE's view is that the success of the messenger model in such circumstances would be dependent on the conditions set out above being met and it acknowledges that this may, in practice, be difficult to achieve in full or, at least, to an acceptable degree of certainty.

Q 2: What safeguards can and would have to be put in place in order to ensure that the messenger model does not facilitate anticompetitive conduct by pharmacy contractors?

Comment

As set out at Q 1 above, it may be difficult to introduce safeguards and measures that guarantee the effective operation of the Messenger Model but we would suggest that the following safeguards would be of assistance:.

- *Independence of the messenger*

A primary concern would be the independence of the messenger. In this regard, we would note that the IPU could not be considered an independent body capable of carrying out the messenger process. The success of the messenger model is ultimately in the hands of the messenger, who must be able to fulfil the role, in a neutral, non-partisan manner.

- *Educating those participating in the process*

  The first step will be to set out clear "Rules of Engagement" for the process, preferably with the endorsement of the Competition Authority. It will then be essential to ensure that those pharmacy contractors participating in the process fully understand what they may and may not do under the messenger model pursuant to competition law.

- *Declaration on oath*

  We would propose that every individual pharmacy contractor would be required to sign a declaration under oath of their compliance with the competition law rules in relation to the messenger process.

- *Sanctions*

  There would need to be effective sanctions against anti-competitive conduct. Obviously, the primary threat of sanction would be that anti-competitive activity could result in a criminal investigation and prosecution by the Competition Authority under section 4 of the Competition Act 2002. There could also be contractual sanctions that the HSE could invoke.

The HSE's view is that although the above safeguards might succeed in reducing the risk, it is not possible to demonstrably ensure that 'independence' will prevail and that collective decision-making in various manifestations will not occur undetected.

Q 3: How can the principle set out in *Arduino/Cipolla* – and applied in *Hickey* – be adapted and applied to fit the pharmacy contractor/HSE context?

Comment

In *Arduino/Cipolla,* the European Court of Justice considered whether competition law precluded a Member State from adopting a legislative measure approving, on the basis of a draft produced by a professional body of lawyers, a scale fixing minimum and maximum fees for members of the legal profession. The Court concluded in essence that the Member State was not in breach of its competition law obligations where it retained the final say on the fee levels. In coming to this conclusion, it noted the particular factual circumstances of the case, including that the lawyers association had to propose a fee scale in accordance with criteria laid down in national legislation, that that scale was subject to the approval of a Minister after seeking the views of a government committee on pricing, that the Minister had the power to reject the proposed scale, and that the exact fees in a particular case were set by a court, who had the discretion to go over or under the scale set.

While, at first glance, there are analogies between *Arduino/Cipolla* and the position under the Pharmacy Contract in that Clause 12 envisages a unilateral decision of the Minister after consultation with the professional body representing pharmacy contractors, it should be emphasised that this analogy only holds good for so long as the final say on prices genuinely lies with the State. It is certainly questionable whether this would be the case where the decision of the State was responded to by threats of collective boycott or other anticompetitive activity jeopardising the continuity of essential public health services.

The second important point to make in relation to *Arduino/Cipolla* is that these cases concerned the liability of the Italian State under the Treaty competition rules; the Court was not asked to consider and did not rule on the compatibility of the behaviour of the Lawyers' Association with Articles 81 and 82 of the Treaty. These judgments cannot be invoked to support the proposition that the actions of pharmacy contractors or the association of pharmacy contractors (the IPU), when developing and finalising their position in relation to fees, are immunised from the application of the Competition Act/EC Treaty. The *Arduino/Cipolla* cases do not change the fact that a collective agreement between pharmacy contractors on the issue of price may be in breach of the Competition Act and Article 81 of the EC Treaty.

The HSE is not able to suggest a way of dealing with the competition law risks identified by the Authority other than by amending Clause 12 of the Pharmacy Contract to provide for decision on fees to be made by the Minister/HSE after consultation with individual pharmacy contractors rather than with a professional body. This would open up the possibility (discussed above) of the engagement with the industry being carried out by way of the messenger model.

Finally, as pointed out by the Authority in the Consultation Paper, the State must remain 'the real decision maker' and, for this to be the case, there cannot be a threat of collective boycott or other anti-competitive action.

Q 4: In particular, what risk-limiting mechanisms can be put in place to ensure that:

(i) pharmacy contractors do not engage in prohibited collective conduct in arriving at a draft fee scale; *and*

(ii) having proposed a draft fee scale to the HSE, pharmacy contractors do not engage in any collective action contrary to section 4(1) of the Competition Act and article 81(1) EC?

Comment

We refer to our responses to Question 2.

(i) Pharmacy contractors must be helped to understand the messenger model and their role in it. The 'rules of engagement' must be clearly documented in advance, with contractors being given clear guidance as regards what behaviour is permissible. The contractual and criminal consequences of infringing competition law must be clearly explained and understood. Individual pharmacy contractors should have to pledge their compliance with competition law under oath. It would be important that, during the process, provider behaviour would be closely monitored, with the Competition Authority investigating and

prosecuting on foot of any breaches and with the HSE invoking available contractual sanctions.

(ii) The real danger is that a 'concerted practice' by providers could arise owing to dissatisfaction with the fee levels proposed by the State. Such action may be manifest in a number of ways, principally through low or nil take-up of the contract and or threatened or actual collective disruption of services. Any agreement to collectively withdraw or threaten to withdraw services would constitute a breach of Irish and EU law. It is difficult to devise arrangements that will prevent such action. The situation would have to be closely monitored and, if necessary, potential breaches investigated and prosecuted by the Competition Authority.

Q 5: Are there non price, output and market terms and conditions of the contractor agreement about which pharmacy contractors wish to engage in collective negotiation?

Comment

While this is a question primarily for pharmacy contractors, the HSE would speculate that pharmacy contractors would wish to negotiate collectively on the dimensions of the contract such as the following:

- Services to be provided;
- Those to whom services are to be provided;
- Standards;
- Clinical issues
- Governance;
- Disciplinary procedures / sanction / appeals;
- Contractor complaints;
- Claims / reimbursement administrative arrangements;
- ICT supports / arrangements;
- Terms and conditions, e.g. leave payments and superannuation scheme;
- Contract management arrangements.

However, while the HSE believes that there are benefits in engaging collectively with pharmacy contractors in relation to non-fee items, for the reasons discussed in the answer to Q.6 below, it is of the view that this engagement should be by consultation rather than negotiation.

Q 6: If so, what is the rationale for setting these terms by collective negotiation?

Comment

Pharmacy contractors may, for obvious reasons, feel that their representative body will be best positioned to represent them in relation to the dimensions of the contract identified above. The HSE acknowledges that there are efficiencies in dealing with one representative organisation, where such conduct is permissible. From the State's perspective, the advantages of a collective approach include:

- Availability of a wide body of experience / knowledge / expertise as an input to various dimensions of the contract;

- Barometer to gauge provider 'buy-in';

- Process to arrive at acceptable form of contract for the State.

- Proposed prescribing/dispensing practices (generics).

However, these objectives are all achievable through a consultation approach rather than a negotiation approach and, for the reasons set out below, the HSE is of the view that the latter is not workable where the fee is to be set after consultation (as opposed to agreement) with the IPU/pharmacy contractors, and that it also raises possible competition law issues.

- It is generally acknowledged that even so-called "non fee issues" can raise competition law concerns. We note the ECJ's comments in Consorzio Indutrie Fiammiferi (CIF) where it observed that *"price competition does not constitute the only effective form of competition or that to which absolute priority must in all circumstances be given"*. A negative effect on competition could flow from a position taken by the IPU in relation to, for example, standards or services to be provided.

- While it might, in an ideal world, be possible to negotiate a firm agreement on the specification with the IPU and then proceed to price this by consultation with the IPU/pharmacy contractors, the reality is somewhat different. Because of the bearing that the details of the specification may have on price and because of budgetary constraints, the State simply has to be in a position to have the final say in relation to the specification of the services it is purchasing. The State must be able to decide not to take up services that prove, ultimately, to be unaffordable.

- Regard must be had to the structure and ownership of community pharmacies which is characterised by chains or multiples, corporate entities and sole traders. It is in the State's interest for all types of pharmacy contractors to have a say in relation to the pharmacy contract. While the HSE recognises the representational role of the IPU on behalf of community pharmacy contractors, it cannot be an exclusive right. The IPU's input must be part of a wider consultative process, open to all current and potential contract holders[7] and involving a number of other relevant stakeholders. None of those involved in the consultation process would have a veto on its outcome, which would be a matter to be determined by the State.

The State's objective is to formulate fair and reasonable terms and conditions that will be acceptable and availed of by pharmacy contractors. For this, a detailed and comprehensive consultation with the IPU as representative body will be essential, but there may also need to be consultation with other stakeholders/the industry generally, and the final decision must rest with the State.

[7] Including pharmacy service providers from other EU member states who have an interest in establishing in Ireland

Q 7: Given the Competition Authority's view that it is not possible to make a declaration pursuant to section 4(3) of the Competition Act exempting collective negotiations between pharmacy contractors and the HSE in relation to the setting of fees, sharing of markets or output restrictions, are there any other categories of agreements, decisions or concerted practices in relation to which the Competition authority might consider making a declaration? Please provide an explanation as to how the suggested agreement, decision or concerted practice satisfies each of the section 4(5) criteria.

Comment

We do not consider that there are any categories of agreements, decisions or concerted practices in respect of which the Competition Authority needs to consider making a declaration. We would have a concern that even so-called "non fee issues" can have a bearing on competition, and that this risk would be difficult to manage in a negotiation. We are of the view, in any event, that the benefits in taking a collective approach on certain matters can equally be attained through a consultative approach, which would not raise the same competition law concerns and which would be more suitable for the reasons explained in our answer to Q. 6.

Signed By:

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28th November 2008